AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in this application:

Listing of claims:

1. (Withdrawn) A process for preparing a fine particulate protein substance or substance mixture, said fine particulate protein substance or substance mixture having a particle size in the nanometer to micrometer range, said process comprises:

grinding a protein substance or substance mixture at a low temperature in a suspending medium, said low temperature being lower than -30°C., wherein said suspending medium is gaseous at ambient pressure and temperature; and

removing said suspending medium.

2. (Withdrawn) The process of claim 1, wherein said suspending medium is an unsubstituted hydrocarbon, a hydrocarbon mono-or -polysubstituted by fluorine, a mixture thereof.

3. (Withdrawn) The process of claim 1, wherein said suspending medium is a hydrocarbon mono- or -polysubstituted by fluorine, selected from the group consisting of TG227, TG134a, TG152a, TG143a, and mixtures thereof.

4. (Withdrawn) The process of claim 1, wherein said suspending medium is an unsubstituted hydrocarbon selected from the group consisting of butane, isobutane, pentane, hexane, heptane and mixtures thereof.

5. (Withdrawn) The process of claim 1, wherein said suspending medium is selected from the group consisting of isobutane, pentane, hexane, heptane, TG227, TG134a, TG152a, TG143a and mixtures thereof.

6. (Withdrawn) The process of claim 1, wherein said low temperature is lower than -40°C.

7. (Withdrawn) The process of claim 1, further comprising adding an excipient to said suspending medium before or after grinding said protein substance or substance mixture, said excipient being selected from the group consisting of lactose, dextrose, sorbitol, mannitol, polyalcohols, xylitol, disaccharides, polysaccharides, –oligosaccharides, dextrins, amino acids, solid lipids, solid phospholipids, vitamins, surfactants, polymers and mixtures thereof.

8. (Withdrawn) The process of claim 1, wherein said protein substance is abarelix, buserelin, cetrorelix, leuprolide, cyclosporine, ganirelix, glucagon, lutropin, insulin, ramorelix, or teverelix.

9. (Currently amended) A solid, fine-particulate pharmaceutical preparation for inhalatory administration to mammals, which comprises a fine particulate protein substance or substance mixture ~~obtained by the process of claim 1~~ prepared by a process comprising the steps of:

a) grinding a protein substance or substance mixture at a low temperature in a suspending medium, said low temperature being lower than -30°C, wherein said suspending medium is gaseous at ambient pressure and temperature; and

b) removing said suspending medium,

wherein 90% of said particulate protein substance having a particle diameter of < 4.9 μm, and protein impurities of said particulate protein substance increased only by 0.08% by the grinding process.

10. (Currently amended) The solid, fine-particulate pharmaceutical preparation of claim 9, wherein said protein substance ~~active compound~~ is abarelix, buserelin, cetrorelix, leuprolide, cyclosporine, ganirelix, glucagon, lutropin, insulin, ramorelix, or teverelix.

11. (Original) The solid, fine-particulate pharmaceutical preparation of claim 9 when filled into a powder inhaler.

12. (Currently amended) The solid, fine-particulate pharmaceutical preparation of claim 11, wherein said powder inhaler is dry powder inhaler (DPI), multi-use dry powder inhaler (MDPI) or a blister inhaler.

13. (Withdrawn) A process for applying a fine-particulate substance or substance mixture to a carrier material, which comprises stripping off by thorough mixing the suspending medium from a suspension of said fine particulate substance or substance mixture, said carrier material and said substance or substance mixture being substantially insoluble in said suspending medium.

14. (Canceled)

15. (Withdrawn) The process of claim 13, wherein said suspending medium is selected from the group consisting of unsubstituted hydrocarbons, hydrocarbons mono- or polysubstituted by fluorine, and mixtures thereof.

16. (Withdrawn) The process of claim 13, wherein said suspending medium is selected from the group consisting of isobutane, pentane, hexane, heptane, TG227, TG134a, TG152a, -TG143a and mixtures thereof.

17. (Withdrawn) The process of claim 13, wherein said carrier material is selected from the group consisting of spherical lactose having a smooth surface, agglomerated lactose having a rough surface, and mixtures thereof.

18. (Withdrawn) The process of claim 13, wherein said fine particulate substance or substance mixture has an average particle size of from about 0.1 to about 10 μm, and said carrier material has an average particle size of from about 10 to about 900 μm.

19. (Withdrawn) The process of claim 13, wherein said suspending medium further contains an excipient selected from the group consisting of lactose, dextrose, sorbitol, mannitol, polyalcohols, xylitol, disaccharides, polysaccharides, oligosaccharides, dextrins, amino acids, solid lipids, solid phopholipids, vitamins, surfactants, polymers and mixtures thereof.

20. (Withdrawn) The process of claim 1, wherein said low temperature is lower than -50°C.

21. (Withdrawn) The process of claim 1, wherein said low temperature is lower than -60°C.

22. (Withdrawn) The process of claim 1, wherein said substance or substance mixture is substantially insoluble in said suspending medium.

23. (Withdrawn) The process of claim 1, wherein said fine particulate protein substance or substance mixture is useful for inhalatory therapy.

24. (Withdrawn) The process of claim 13, wherein said suspending medium is selected from the group consisting of TG227, TG134a, TG152a, TG143a and mixtures thereof.

25. (New) A solid, fine-particulate pharmaceutical preparation for inhalatory administration to mammals, which comprises a fine particulate protein substance or substance mixture, wherein 90% of said particulate protein substance having a particle diameter of < 4.9 μm, and 0.08% increased protein impurities.

26. (New) The solid, fine-particulate pharmaceutical preparation of claim 25, wherein said particulate protein substance having a volume mean diameter of 2.5 μm.